



UNITED STATES PATENT AND TRADEMARK OFFICE

Cg
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,319	06/20/2003	Jay M. Short	09010-029011	6967

25225 7590 08/27/2007
MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
----------	--------------

1652

MAIL DATE	DELIVERY MODE
-----------	---------------

08/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,319	SHORT ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,11,12,20-22 and 50-73 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,11,12,20-22 and 50-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/20/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Status of the Application

Claims 1-3, 6, 11-12, 20-22, 50-73 are pending.

Applicant's amendment of claims 1, 3, 6, 50-56, 63-68, and addition of claims 69-73 as submitted in a communication filed on 6/20/2007 are acknowledged.

New claims 69-73 are directed to the elected subject matter. Claim 6 is rejoined for examination as it is now a generic claim depending on claim 1. Claim 3 remains withdrawn from consideration as linking claim 1 is not yet allowable. Claims 1-2, 6, 11-12, 20-22, 50-51, 53-64, 66-67, 69-73 and claims 52, 65, 68 in part are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claims 52, 65, 68 remain objected to as being directed in part to non-elected inventions.

Appropriate correction is required.

2. Claim 53 is objected to due to the recitation of "wherein phytase comprises..". It should be amended to recite "wherein the phytase comprises...". Appropriate correction is required.

3. Claim 57 remains objected to due to the recitation of "wherein the nucleic acid wherein the nucleic acid". This should be amended to recite "wherein the nucleic acid" only once. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1652

5. Claims 1-2, 6, 11-12, 20-22, 50-68 remain rejected and new claims 69-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. New grounds of rejection are being introduced.

6. Claims 1-2, 51, 53, 55, 66 (claims 6, 11-12, 20-22, 50, 52, 54, 56-65, 69-73 dependent thereon) are indefinite in the recitation of "non-natural or synthetic form of the nucleic acid of" for the following reasons. While the term "synthetic form of the nucleic acid" is understood as a nucleic acid having the same nucleotide sequence as that of the isolated nucleic acid but produced by chemical synthesis, the term "non-natural" is unclear because one cannot determine if the term is intended to encompass a nucleic acid having the same nucleotide sequence as that of the isolated nucleic acid (i.e., naturally-occurring). It is noted that in the absence of a definition of the term, one of skill in the art can reasonably conclude that the term "non-natural form of the nucleic acid" encompasses variants of the isolated nucleic acid with different nucleotide sequences since a non-natural form of the nucleic acid can be a non-naturally occurring variant of the isolated nucleic acid. For examination purposes, the term "non-natural form of the nucleic acid" will be interpreted as encompassing variants of the wild-type *E. coli* nucleic acid recited. Correction/clarification is required.

7. Claim 66 (claims 67-68 dependent thereon) is indefinite in the recitation of "the phytase of (a), (b), or (c) further comprising a coding and/or non-coding sequence or a sequence encoding an amino acid sequence" because a phytase is a protein and the term "coding and/or non-coding sequence or a sequence encoding an amino acid sequence" refers to a nucleotide sequence. A protein does not comprise a nucleotide sequence. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-2, 11-12, 20-22, 50-68 remain rejected and claims 6, 69-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. New grounds of rejection are being introduced.

10. Applicant submits that the current amendments to the claims address the Examiner's concerns regarding the genus of nucleic acids recited to encompass any nucleic acid encoding a phytase.

11. Applicant's arguments have been fully considered. The Examiner acknowledges Applicant's amendment of the claims. However, claims 1-2, 6, 11-12, 20-22, 50-73 are still directed to a method which requires the expression of a genus of variants of an *E. coli* phytase having any structure in view of the interpretation given to the term "non-natural form of the nucleic acid". See extensive discussion above regarding this term. Thus, while new grounds of rejection are being introduced in view of how the term "non-natural" is being interpreted, the same arguments previously presented by the Examiner still apply to the instant claims as the method still requires a genus of species which are structurally unrelated. Therefore, for the reasons extensively discussed in prior Office actions, one of skill in the art cannot reasonably conclude that the genus of nucleic acids required to practice the claimed invention is adequately described by the teachings of the specification.

12. Applicant has indicated in the Response filed on 6/20/2007 that while the Office alleges that claims 11-12 encompass the same genus of nucleic acids required by the method of claim 1, in fact, claims 11-12 merely enumerate exemplary yeast cells that can be used to express the nucleic acids

Art Unit: 1652

recited. Applicant asserts that claims 11-12 do not further limit any of the nucleic acids used in the method of claim 1.

13. The Examiner acknowledges Applicant's comments but fails to determine how the statements made in the previous Office action are in any way in contradiction with Applicant's remarks. The Examiner agrees that claims 11-12 do not further limit the genus of nucleic acids to be used in the method of claim 1 but rather place limitations on the genus of yeast cells used for expression. This is the reason why the Examiner indicated in the prior Office action that claims 11-12 encompass the same genus of nucleic acids required by the method of claim 1. The term "encompass" as used in the Examiner's statement was intended to mean "require". The Examiner did not intend by this statement to indicate that the entire scope of claims 11-12 is the same as that of claim 1 (i.e., duplicate claims), or that claims 11-12 are directed to a genus of nucleic acids. Instead, the Examiner's statement was intended to point to the main issue that led the Examiner to also reject claims 11-12 as failing to meet the written description requirement, i.e., the genus of nucleic acids required by the claimed method. With regard to the genus of nucleic acids required by the claimed invention, the scope of claims 1, 11-12 is identical since, as correctly pointed out by Applicant, claims 11-12 do not limit the scope of the genus of nucleic acids recited in claim 1. Thus, the Examiner believes her previous statements regarding the scope of claims 11-12 and Applicant's remarks are in agreement.

14. Applicant also points out that the Examiner incorrectly indicated that the phytases of SEQ ID NO: 2 and 10 are man-made. The Examiner agrees. Upon careful review of the specification, it has been found that the phytase of SEQ ID NO: 2 is a wild-type *E. coli* phytase from *E. coli B* whereas the polypeptide of SEQ ID NO: 10 is a man-made variant. The Examiner regrets the confusion that this statement may have caused.

Art Unit: 1652

15. Claims 1-2, 11-12, 20-22, 50-68 remain rejected and claims 6, 69-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method to recombinantly produce the polypeptide of SEQ ID NO: 10 in yeast cells, does not reasonably provide enablement for a method to recombinantly produce any phytase in yeast cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. New grounds of rejection are being introduced.

16. Applicant submits that the current amendments to the claims address the Examiner's concerns regarding the genus of nucleic acids recited encompassing any nucleic acid encoding a phytase.

17. Applicant's arguments have been fully considered. The Examiner acknowledges Applicant's amendment of the claims. However, as indicated above, the instant claims are still directed to a method which requires the expression of any variant of an *E. coli* phytase having any structure in view of the Examiner's interpretation given to the term "non-natural form of the nucleic acid". See above for additional discussion. Even though new grounds of rejection are being introduced in view of how the term "non-natural" is being interpreted, the same arguments previously presented in prior Office actions are still applicable to the instant claims as the method still requires a genus of species which are structurally unrelated. Therefore, for the reasons set forth in prior Office actions, one of skill in the art cannot reasonably conclude that the entire scope of the claimed invention is enabled by the teachings of the specification and/or the prior art.

Claim Rejections - 35 USC § 102

18. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1652

19. Claims 1-2, 11-12, 20-22, 51, 53-62, 66 remain rejected and claims 6, 50, 52, 63-65, 67-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Berka et al. (U.S. Patent No. 5866118, issued 2/2/1999, filed 3/18/1997). New grounds of rejection are being introduced.

20. This rejection has been discussed at length in the Non Final action mailed on 7/25/2006 and the Non Final action mailed on 1/29/2007.

21. Applicant argues that the claims have been amended such that the method is limited to the production of the phytase of SEQ ID NO: 10 or wild-type *E. coli* phytases. Since Berka et al. do not teach such method, this rejection should be withdrawn.

22. Applicant's arguments have been fully considered but are not deemed persuasive. The instant claims are not solely directed to a method to recombinantly produce the polypeptide of SEQ ID NO: 10 or wild-type *E. coli* phytases due to the recitation of the term "non-natural". In view of the interpretation given to this term, the instant claims are still directed to a method for recombinantly produce any variant of an *E. coli* phytase in yeast cells. See Claim Rejections under 35 USC 112, second paragraph for extensive discussion of claim interpretation. Since the claims require a genus of nucleic acids encoding any variant of an *E. coli* phytase, the claims essentially require a genus of nucleic acids encoding any phytase because there are no structural limitations imposed. A variant of an *E. coli* phytase having sequence X cannot be distinguish structurally or functionally from a phytase isolated from another organism which also has sequence X, in view of the fact that the amino acid sequence of a protein determines its functional characteristics. Thus, even if Berka et al. discloses the recombinant production of a phytase from an organism which is not *E. coli*, the teachings of Berka et al. still anticipate the instant claims as written. It is also noted that claims 50, 52, 63-65, 67-73 are also anticipated by the teachings of Berka et al. in view of the fact that these claims do not limit the polypeptide to be made to that of SEQ ID NO: 10 or 2. These claims still require the nucleic acid of (i)(b). Thus, for the reasons discussed above and those of record, the teachings of Berka et al. anticipate the instant claims.

Claim Rejections - 35 USC § 103

23. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

24. Claims 1-2, 11-12, 20-22, 51, 53-62, 66 remain rejected and claims 6, 50, 52, 63-65, 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostanin et al. (J. Biol. Chem. 267(32):22830-22836, 1992; cited in the IDS) in view of Berka et al. (U.S. Patent No. 5866118, issued 2/2/1999, filed 3/18/1997). New grounds of rejections are being introduced.

25. Applicant argues that Ostanin et al. do not teach recombinant production in yeast cells and Berka et al. do not teach the production of a naturally-occurring *E. coli* phytase. Applicant asserts that because Berka et al. cannot be used to cure the deficiencies in Ostanin, this rejection should be withdrawn.

26. Applicant's arguments have been fully considered but are not deemed persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Berka et al. provides a method for the production of a phytase in yeast cells. The only limitation missing in the teachings of Berka et al. is an *E. coli* phytase, which is clearly taught by Ostanin et al. In addition, Ostanin et al. teach a method for the recombinant production of the *E. coli* phytase in *E. coli* cells. As indicated in the previous Office action, a person of ordinary skill in the art is motivated to produce the phytase in yeast because, as known in the art, production of recombinant proteins in yeast is highly desirable as this expression host cell allows for efficient secretion of the recombinant protein to the extracellular medium, thus providing a product which is easier to purify. One of ordinary skill in the art has a reasonable expectation of success at expressing the nucleic acid of Ostanin et al. in yeast since Berka et al. teach different yeast cells and expression vectors for recombinant

Art Unit: 1652

protein production as well as the fact that expression in yeast cells is well known and widely used in the art. Therefore, the combined teachings of Berka et al. and Ostanin et al. render the claimed invention prima facie obvious to a person of ordinary skill in the art.

It is noted that the teachings of Berka et al. and Ostanin et al. render the invention of claims 50, 52, 63-65, 67-73 obvious in view of the fact that these claims do not limit the phytase to be made to a particular naturally-occurring *E. coli* phytase. These claims still require the wild-type *E. coli* nucleic acid of (i)(a) with no structural limitations, including claims 52, 65 and 68, in view of the fact that the phrase "or the sequence of (i) has the sequence of SEQ ID NO: 1, or encodes the amino acid sequence of SEQ ID NO: 2" as recited in claims 52, 65, and 68 is an alternative term that allows for the methods of claims 51, 55, and 66 not to require the wild type *E. coli* phytase to be that of SEQ ID NO: 2.

Double Patenting

27. Claims 1, 11-12, 50, objected to under 37 CFR 1.75 as being a substantial duplicate of claims 51, 61-63. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 1 requires the nucleic acid to be expressed. Claim 50 requires the nucleic acid to be operably linked to a promoter. As known in the art, for expression to occur, a promoter is required. Therefore, the nucleic acid of claim 1 is the same as that of claim 50 since the nucleic acid of claim 1 would require a promoter to be expressed.

Art Unit: 1652

Allowable Subject Matter

28. A method to recombinantly produce the polypeptide of SEQ ID NO: 10, wherein said method requires culturing a yeast cell transformed with a polynucleotide encoding the polypeptide of SEQ ID NO: 9, is allowable over the prior art of record.

Conclusion

29. No claim is in condition for allowance.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652